Apremilast for the treatment of moderate-to-severe psoriasis: Real-world data from the Czech Republic BIOREP Registry

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INTRODUCTION

- Apremilast is an oral non-biological phosphodiesterase-4 inhibitor and has been approved for the treatment of moderate-to-severe plaque psoriasis; however, real-life evidence is still limited
- The aim of this study was to evaluate apremilast treatment in the real-world setting by analyzing data from the Czech Republic BIOREP Registry.

MATERIAL AND METHODS

- BIOREP is a national registry of patients with inflammatory skin diseases (psoriasis, hidradenitis suppurativa and atopic dermatitis) treated with targeted therapy in the Czech Republic. The registry was established in 2005 to monitor the long-term efficacy and safety of targeted treatment of psoriasis.
- We analyzed the cohort of patients on apremilast therapy until January 2023.

RESULTS

- The study included 349 apremilast patients with moderate-to-severe psoriasis.
- Patients were predominantly male (55.0%); mean time from diagnosis to initiation of apremilast therapy was 23.2 years. Psoriatic arthritis was present in 25.2% of patients. Before starting treatment, patients were most often treated with methotrexate (80.8%) and/or phototherapy (70.2%), and a total of 13.5% of patients were treated with biologics. (Table 1)
- The mean PASI at baseline was 15.5 (SD 6.2) and was decreased to 2.5 (SD 3.0), 2.4 (SD 3.1), 1.9 (SD 2.8) and 1.1 (SD 1.1) after 12, 24, 36 and 48 months. Similarly, a decrease in DLQI was observed at 12 months from 14.9 (SD 6.3) to 2.6 (SD 3.0) with average values from 3.1 to 1.3 until 48 months. At 4, 12, 24, 36 and 48 months of treatment, a total of 87.8%, 92.5%, 92.5%, 94.4% and 100.0% of patients achieved PASI 50; 59.7%, 68.8%, 80.0%, 83.3% and 90.0% of patients reached PASI 75; 24.9%, 50.5%, 45.0%, 61.1% and 70.0% achieved PASI 90, and 12.2%, 25.8%, 20.0%, 27.8% and 30.0% of patients achieved PASI 100, respectively. (Table 1, Figure 1 – 3)
- The therapy was discontinued in 69.4% treatment series (loss of effectiveness in 51.6%, adverse events in 6.5%). (Table 2)
- Predicted drug survival probability at 12, 24, 36 and 48 months of treatment was 42.9%, 19.6%, 10.8% and 8.3%, respectively. Patients with psoriatic arthritis had on average 33.1% (95% CI 8.6-51.0%) lower risk of discontinuation apremilast treatment compared to patients without PsA, no difference in survival probability was found according to naivety, gender, or obesity. (Figure 4. A-E)

Table 1. Baseline characteristics

	N/Mean	%/SD
Number of patients	349	
Men	192	55.0%
Age (years)	53.4	14.3
Age at the time of diagnosis	28.2	15.9
Age at the time of initiation of apremilast	51.4	14.3
Duration of psoriasis (years)	25.2	15.1
Duration from diagnosis to the initiation of apremilast	23.2	15.0
Family history of psoriasis	134	38.4%
BMI (kg/m^2)	29.3	6.2
BMI category		
Underweight (<18.5)	4	1.1%
Normal (18.5–24.99)	89	25.5%
Overweight (25–29.99)	113	32.4%
Obese (≥30)	143	41.0%
Psoriatic arthritis	88	25.2%
At least one comorbidity	237	67.9%
Selected comorbidities		
Hypertension	124	35.5%
Dyslipidemia	93	26.6%
Diabetes mellitus	61	17.5%
Depression	20	5.7%
Malignancy	45	12.0%
Smokers	116	33.2%
Ex-smokers	67	19.2%
Previous systemic therapy		
Phototherapy	245	70.2%
Methotrexate	282	80.8%
Retinoid	195	55.9%
Cyclosporine	102	29.2%
Other	28	8.0%
Previous biologic therapy (Yes)	47	13.5%
Anti-TNF	20	5.7%
IL-12/23	12	3.4%
IL-17	14	4.0%
IL-23	1	0.3%
PASI	15.5	6.2
DLQI	14.9	6.3

Values are n (%) of patients or mean (± SD); BMI, Body Mass Index

PASI, Psoriasis Areaand Severity Index; DLQI, Dermatology Life Quality Index

Figure 2. PASI improvement

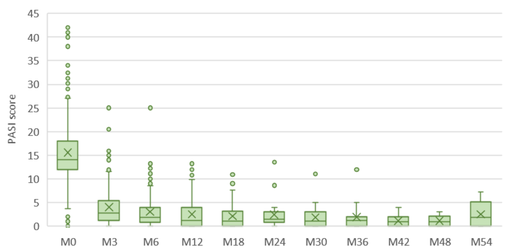


Figure 3. DLQI improvement

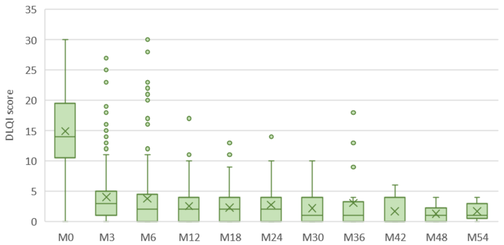


Figure 4. Drug survival A) All subjects B) Naïve/experienced

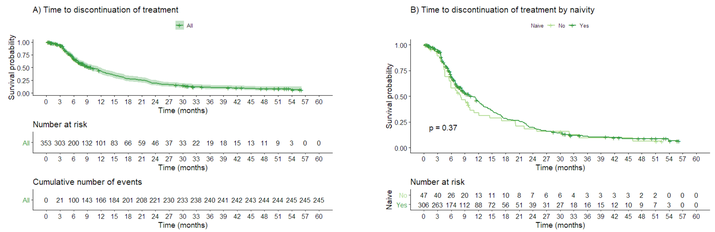


Figure 4. Drug survival C) By sex D) By PsA at baseline (yes/no) E) By obesity

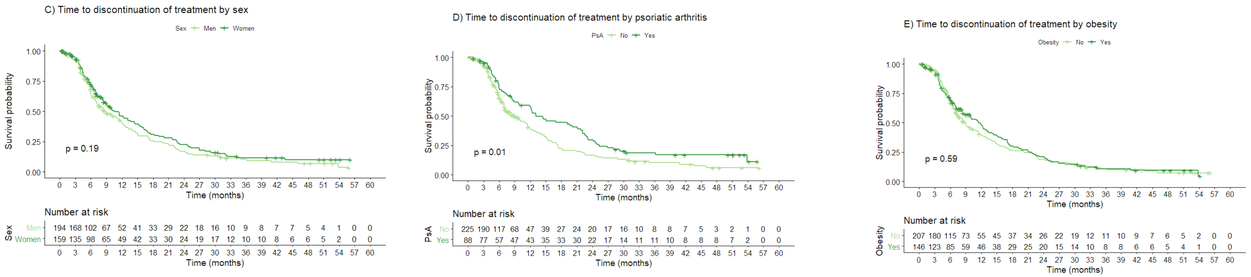
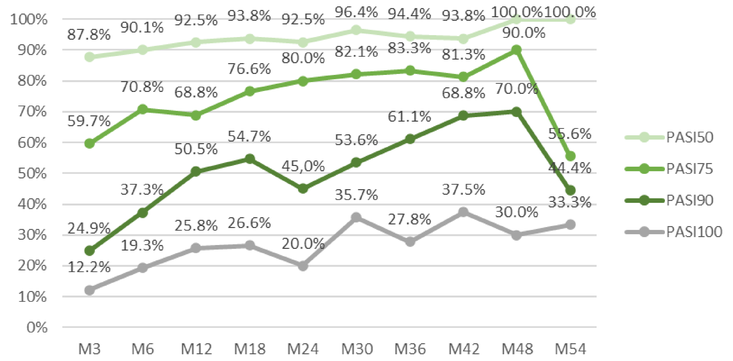


Figure 1. PASI improvement (50, 75, 90, 100)



DISCUSSION

In this analysis of real-world data, patients initiating apremilast therapy had severe disease with a high impact on quality of life at baseline. Data indicate high rates of clearance and improvement in quality of life in patients with psoriasis on apremilast therapy. Our analysis fills the gap of efficacy, safety, and survival probability for apremilast treatment from real clinical practice.

Table 2. Discontinuation of therapy

Reason for discontinuation	N	%
Loss of efficacy	182	51.6%
Adverse Events	24	6.8%
Loss of reimbursement	18	5.1%
Patient´s wish	8	2.3%
Patient non-cooperation	3	0.8%
Pregnancy	2	0.6%
Economic reason	3	0.8%
Surgery	1	0.3%
Death	1	0.3%
Other	3	0.8%
Total	245	69.4%

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